IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
DALLAS DIVISION

CARL LUCAS, JR. and BETTYE CLAY,	)	
	)	
Plaintiffs,	)	
	)	Case No. 3:12-cv-03654-D
v.	)	
	)	Hon. Sidney A. Fitzwater
ABBOTT LABORATORIES,	)	
	)	
Defendant.	)	

JOINT STATUS REPORT AND SCHEDULING PROPOSAL

The parties conducted a status and scheduling conference for this matter on October 29, 2012. Although the order required a 26(f) conference in person and seven days prior to the October 29, 2012 date, attorney Jonathan Rawlins attended the conference telephonically on behalf of Plaintiffs Carl Lucas Jr. and Bettye Clay, and attorney Bryan Pollard attended the conference on behalf of Defendant Abbott Laboratories. The delay in completing the required conference was solely due to circumstances surrounding Plaintiffs' counsel and his employ and was by no fault of Plaintiffs themselves, Defendant or Defendant's counsel. At the courts request, Plaintiffs' counsel will gladly issue a statement to the court explaining the situation. After Plaintiffs' counsel Jonathan Rawlins explained these circumstances to defense counsel, counsel for the parties conducted the conference by telephone.

As a preliminary matter, the parties notify the Court that, on October 15, 2012, District 6 of the Texas State Bar Grievance Committee to disbar Plaintiffs' lead counsel, Thomas Corea, from the practice of law in the State of Texas. The parties attach a copy of the Grievance Committee's Judgment of Disbarment as *Attachment 1*.

1. **Brief Statement of the Case and Contentions of the Parties**.

This is a diversity jurisdiction, personal injury products liability case. The case concerns the use of Abbott's prescription drug Humira by plaintiff Carl Lucas Jr. for hidradenitis suppurativa (a severe form of acne). It is alleged that Mr. Lucas' Humira use resulted in a lupus-like syndrome and opportunistic infections.

a. ***Plaintiffs' Position***

Plaintiffs contend that Abbott Laboratories promoted the drug Humira for non FDA-approved purposes. As a result of Abbott's "off-label" promotions, Carl Lucas was ultimately prescribed and used Humira for a purpose not approved by the FDA. Mr. Lucas's use of Humira for "off-label" purposes resulted in serious side effects that have caused and continue to cause him severe physical pain and suffering as well as severe permanent disfigurement. Mr. Lucas has undergone several major surgeries to attempt to repair the damage caused by his Humira use and has many more surgeries to come. Mr. Lucas and his mother Betty Clay have both suffered severe emotional distress and depression caused by the traumatic side effects of Mr. Lucas's Humira use.

b. ***Defendant's Position***

First, Abbott Laboratories states that the FDA-approved package insert for Humira in effect at the time Carl Lucas Jr. was allegedly prescribed Humira in December 2009 adequately warned of the potential increased risk of opportunistic infections and a lupus-like syndrome:

> **WARNING: RISK OF SERIOUS INFECTIONS**
> Tuberculosis (frequently disseminated or extrapulmonary at clinical presentation), invasive fungal infections, and other opportunistic infections, have been observed in patients receiving HUMIRA. Some of these infections have been fatal.

5 WARNINGS AND PRECAUTIONS

5.1 Serious Infections

Serious infections, sepsis, tuberculosis and cases of opportunistic infections, including fatalities, have been reported with the use of TNF blocking agents including HUMIRA. Many of the serious infections have occurred on concomitant immunosuppressive therapy that, in addition to their rheumatoid arthritis could predispose them to infections…

Treatment with HUMIRA should not be initiated in patients with active infections including chronic or localized infections. Patients who develop a new infection while undergoing treatment with HUMIRA should be monitored closely. Administration of HUMIRA should be discontinued if a patient develops a serious infection. Physicians should exercise when considering the use of HUMIRA in patients with a history of recurrent infection or underlying conditions which may predispose them to infections, or patients who have resided in regions where tuberculosis and histoplasmosis are endemic. The benefits and risks of HUMIRA treatment should be carefully considered before initiation of HUMIRA therapy.

5.9 Autoimmunity

Treatment with HUMIRA may result in the formation of autoantibodies and, rarely, in the development of a lupus-like syndrome. If a patient develops symptoms suggestive of a lupus-like syndrome following treatment with HUMIRA, treatment should be discontinued. [see Adverse Reactions (6.1)]

* * *

6 ADVERSE REACTIONS

6.1 Clinical Studies Experience

- Serious Infections
- Neurologic Reactions
- Malignancies

Infections

In placebo-controlled rheumatoid arthritis trials, the rate of infection was 1 per patient-year in the HUMIRA-treated patients and 0.9 per patient-year in the placebo-treated patients. The infections consisted primarily of upper respiratory tract infections, bronchitis, and urinary tract infections. Most patients continued on HUMIRA after the infection resolved. The incidence of serious infections was 0.04 per patient-year in HUMIRA treated patients and 0.02 per patient-year in placebo-treated patients. Serious infections observed included pneumonia, septic arthritis, prosthetic and post-surgical infections, erysipelas, cellulitis, diverticulitis, and pyelonephritis. [*see Warnings and Precautions (5.1)*].

> *Autoantibodies*
>
> In the rheumatoid arthritis controlled trials, 12% of patients treated with HUMIRA and 7% of placebo-treated patients that had negative baseline ANA titers developed positive titers at week 24. Two patients out of 3046 treated with HUMIRA developed clinical signs suggestive of new-onset lupus-like syndrome. The patients improved following discontinuation of therapy. No patients developed lupus nephritis or central nervous system symptoms. The impact of long-term treatment with HUMIRA on the development of autoimmune disease is unknown.
>
> * * *
>
> **Before starting HUMIRA, tell your doctor if you:**
>
> - think you have an infection.
> - are being treated for an infection
> - have signs of an infection, such as fever, cough, or flu-like symptoms
> - have any open cuts or sores on your body
> - get a lot of infections or have infections that keep coming back
>
> **After starting HUMIRA,** if you get an infection, any sign of an infection including a fever, cough, flu-like symptoms, or have any open cuts or sores on your body, **call your doctor right away.**
>
> HUMIRA can make you more likely to get infections or make any infection that you may have worse.
>
> **What are the possible side effects of HUMIRA?**
>
> - **Serious infections**
> - **Immune reactions including lupus-like syndrome.** Symptoms include shortness of breath, joint pain, or rash on your cheeks or arms that is sensitive to the sun. Symptoms may go away when you stop HUMIRA.

These FDA-approved warnings are presumptively adequate as a matter of Texas law. TEX. CIV. PRAC. & REM. CODE § 82.007.

Second, under Texas Law, the learned intermediary doctrine applies to all of Plaintiffs' failure to warn claims. Under the doctrine, Abbott's duty to warn runs to the prescribing physician. Causation is an essential element of a failure-to-warn claim and requires that

Plaintiffs show that a proper warning would have changed the decision of the intermediary to prescribe the product. Plaintiffs will be unable to show that additional warnings would have changed the decision of the prescribing physician to prescribe Humira.

Third, Abbott asserts that plaintiffs cannot state a viable claim for negligence per se because courts applying Texas law do not recognize such a cause of action under the Federal Drug and Cosmetic Act ("FDCA") and accompanying regulations. Plaintiffs also cannot state a viable claim under the Deceptive Trade Practices Act ("DPTA") because the DTPA does not apply to claims for bodily injury or mental anguish. Finally, plaintiff Betty Claye cannot recover for loss of consortium of companionship because recovery for services of an adult child is not available under Texas law.

Abbott will assert additional defenses as they become known through the course of discovery.

2. **Status of Settlement Discussions**

Plaintiffs have presented Abbott with a written settlement demand for their DTPA claim. No other settlement demands have been presented. At this time, no agreement can be reached.

3. **Jurisdiction and Venue**

The parties do not anticipate challenges to jurisdiction and venue.

4. **Date By Which The Case Will Be Ready For Trial And Estimated Length Of Trial.**

The parties estimate that this case will be ready for trial by February 2014 and estimate a trial of approximately fourteen days.

5. **Joint Proposal For Discovery And Other Deadlines**.

The parties propose the following schedule:

Initial Disclosures	November 29, 2012

Deadline to File Motion to Amend Pleadings	February 1, 2013
Completion of Fact Discovery	June 17, 2013
Designation of Plaintiffs' Trial Experts and Service of Plaintiffs' Expert Reports	July 19, 2013
Designation of Defendant's Experts and Service of Defendant's Expert Reports	August 23, 2013
Completion of Expert Depositions	September 27, 2013
Deadline to File Dispositive Motions	November 1, 2013
Deadline to File Oppositions to Dispositive Motions	December 6, 2013

6. **Desirability and Timing for ADR**

At this time, the parties do not desire to participate in ADR. As the case progresses, the parties' position on ADR may be subject to change.

7. **Objections to Initial Disclosures Under Rule 26(a)(1)**

The parties do not object to Rule 26(a)(1) disclosures and intend to exchange initial disclosures on or before November 29, 2012. Defendant Abbott Laboratories' initial disclosures will be served without prejudice to the positions it asserts in its pending motion for judgment on the pleadings on the grounds that Plaintiffs' complaint has failed to state a claim upon which relief can be granted.

8. **Magistrate Judge**

The parties do not consent to trial before a U.S. Magistrate Judge.

Rule 26(f)(3) Discovery Plan

(A) What changes should be made in the timing, form, or requirement for disclosures under Rule 26(a), including a statement of when initial disclosures were made or will be made.

The parties agree that they will complete initial disclosures as required by Rule 26(a)(1) by November 29, 2012. The parties suggest no other changes to the timing, form, or requirement for disclosures under Rule 26(a).

(B) The subjects on which discovery may be needed, when discovery should be completed, and whether discovery should be conducted in phases or be limited to or focused on particular issues.

The parties agree that discovery in this case will include extensive document production on the labeling of Humira, collection of medical records from third-party healthcare providers, and fact witness depositions (to include treating healthcare providers).

Defendant Abbott Laboratories' position is that, in light of its pending motion for judgment on the pleadings, no other discovery than service of the parties' Rule 26 initial disclosures should take place until that motion is decided. Defendant Abbott Laboratories anticipates that the discovery Plaintiffs plan to seek from it is likely to be extensive and voluminous, imposing significant burdens on Abbott Laboratories. Given that Abbott Laboratories contends that Plaintiffs have stated no legally valid claim against it, it would be inappropriate for discovery to proceed unless the Court rules that there is a basis upon which Plaintiffs' action against Abbott Laboratories can be maintained.

(C) Any issues about disclosure or discovery of electronically stored information, including the form or forms in which it should be produced.

The parties do not anticipate disputes concerning the disclosure or discovery of electronically stored information, including the form or forms in which it should be produced.

(D) Any issues about claims of privilege or of protection as trial-preparation materials, including — if the parties agree on a procedure to assert these claims after production — whether to ask the court to include their agreement in an order.

The parties contemplate the need for a protective order to address confidentiality issues in this case, and may also address issues concerning privilege in that order.

(E) What changes should be made in the limitations on discovery imposed under these rules or by local rule, and what other limitations should be imposed.

The parties do not currently believe any changes to the limitations on discovery are necessary in this case.

(F) Any other orders that the court should issue under Rule 26(c) or under Rule 16(b) and (c).

The parties do not currently believe there is a need for other orders under Rules 16(b) and (c), but, as stated above, they seek a protective order under Rule 26(c) to address confidential documents.

Respectfully submitted,

s/ Jonathan E. Rawlins (with permission)

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CERTIFICATE OF SERVICE

I hereby certify that, on October 29, 2012, I electronically submitted the foregoing document with the clerk of court for the U.S. District Court, Northern District of Texas, using the electronic case filing system of the court. I hereby certify that I have served all counsel of record electronically or by another manner authorized by Federal Rule of Civil Procedure 5 (b)(2).

Bryan D. Pollard